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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,055

04/27/2005

Minoru Takebe

211A 3658 PCT

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3713

7590

04/23/2008

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,055	Applicant(s) TAKEBE ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 11, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed February 11, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 1 and 5 under 35 U.S.C. 102(e) as being anticipated by Obata et al. (U.S. Patent No. 6,444,239 B2) is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 1 under 35 U.S.C. 102(b) as being unpatentable by The Merck Index, tenth edition. (1983) is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claim 1 under 35 U.S.C. 102(b) as being unpatentable by Potter et al. (U.S. Patent No. 5,855,892) is being **maintained** for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed February 11, 2008 have been fully considered but they are not persuasive. Applicants argue that the teachings of Merck reference is nothing more than an encyclopedia of chemicals, drugs and biological and does not

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teach anything about the concentrations of compositions of the chemicals, drugs and biological contained therein and does not disclose the superoxide scavenging activity.

This is not found persuasive because giving the claims the broadest reasonable interpretation, the instant claim reads on the pure compound of daidzein. It is noted that the pure daidzein compound disclosed by Merck meets all the physical requirements set forth in the claim because it is a pure compound having 100% of daidzein. Applicants argument that Merck does not disclose superoxide scavenging activity is not persuasive because Applicants' recitation of the composition having a superoxide scavenging activity of 12000 units/g would be inherent property of the same composition taught by cited prior art comprising pure form of the same active agent of isoflavone aglycone comprising overlapping and encompassing the instantly claimed amounts as being a pure compound having 100% daidzein. It is noted that there is no upper limit to the content of the isoflavone aglycone set forth in the claims.

With respect to Applicants' argument regarding Potter's Formulations 1 through 3, Applicants state that Formulation 1 has 1000mg of active ingredient which is less than 50% of 2,220mg total composition; Applicants state that Formulation 2 also have 1,000mg of active ingredient of 1,865mg total composition, which is less than 70%; and Applicants state that Formulation 3, where would be 1000mg of active ingredient of a total of 1,715mg, which is again, less than 70% active ingredient. This is not found persuasive because Formulations of Potter et al. have been carefully reviewed. It is noted that instant claim only requires **at least 30% of isoflavone aglycone** in total composition. And at least 70% of those 30% isoflavone aglycone concentrate in the

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composition is daidzein. (see instant claim 1). Therefore, the claimed subject matter is clearly anticipated by these formulations. That is, Formulation 1, 2, and 3 as stated by Applicants containing 1000mg of active ingredient meets Applicants requirement of at least 30% isoflavone aglycone because the total weight of the formulations 1, 2 and 3 are 2,220mg, 1,865mg, and 1,715mg as stated by the Applicants. Further, the daizein content calculated by the Applicants' above are at least 70% of the 30% isoflavone aglycone in the Potter's formulations. Accordingly, Applicants' recitation in claim 1, the composition having a superoxide scavenging activity of 12000 units/g would be inherent property of the same composition taught by Potter's formulation comprising the same active agent, isoflavone aglycone comprising overlapping and encompassing the instantly claimed amounts. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Objections

Claim 1 is objected to because of the following informalities: The term "daidzein" appears to be misspelled as "diadzein". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being unpatentable by The Merck Index, tenth edition. (1983), (Merck).

Merck teaches that daidzein obtained from soybean. It is noted that the content of (pure) daidzein taught by prior art encompasses Applicant's amount set forth in claims 3 and 5.

Accordingly, Applicant's recitation in claim 1 of the composition having a superoxide scavenging activity of 12000 units/g would be inherent property of the same composition taught by cited prior art comprising pure form of same active agent of isoflavone aglycone (daidzein) comprising overlapping and encompassing the instantly claimed amounts. Further, Applicants' recitation in claim 1 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition taught by the prior art.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being unpatentable by Potter et al. (U.S. Patent No. 5,855,892).

Potter et al. teach pharmaceutical formulation of daidzein as an active agent. Potter et al. teach gelatin capsules comprising 10-1000mg of daidzein in a capsule and a tablet. Potter et al. also teach daidzein in 10-1000mg/5ml in a suspension. (column

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7, under Formulations and formulations 1-3). These amounts of daidzein contained in the formulations overlap and encompasses Applicants' claimed amount of isoflavone aglycone at least 30%wt and at least 70wt% daidzein.

Accordingly, Applicant's recitation in claim 1 of the composition having a superoxide scavenging activity of 12000 units/g would be inherent property of the same composition taught by cited prior art comprising same active agent of isoflavone aglycone (daidzein) comprising overlapping and encompassing the instantly claimed amounts. Further, Applicants' recitation in claim 1 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition taught by the prior art.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
April 21, 2008